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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/492,702	01/27/2000	ZYSKIND	J ELITRA.001A

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EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1631	8

DATE MAILED: 06/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/492,709	Zyskind et al.
Examiner	**Art Unit**
Ardin Marschel	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-110 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-110 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☒ The ~~proposed~~ drawing(s) ~~correction~~ filed on Jan 27, 2000 are: a) ☒ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other *RAW SEQUENCE LISTING ERROR REPORT*

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because or errors listed on the enclosed RAW SEQUENCE LISTING ERROR REPORT. Applicants are required to submit a new computer readable form sequence listing, paper copy for replacing the present paper sequence copy in the specification, and a new statement under 37 CFR § 1.821(f). Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to comply may result in abandonment of this application.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-16, 52, 53, and 106; drawn to polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; Class 435, subclasses 243, 320.1, and 325; and Class 514, subclass 44. If this group is elected, then the below

sequence election requirement also is required.

II. Claims 17 and 18, drawn to polypeptides, classified in Class 530, subclass 350. If this group is elected, then the below sequence election requirement also is required.

III. Claim 19, drawn to an antibody, classified in Class 530, subclass 387.1. If this group is elected, then the below sequence election requirement also is required.

IV. Claims 20 and 21, drawn to methods of expression of polypeptides from polynucleotides, classified in Class 435, subclass 69.1. If this group is elected, then the below sequence election requirement also is required.

V. Claims 22, 48-51, and 54-65; drawn to methods of inhibiting proliferation, classified in Class 514, subclasses 2 and 44. If this group is elected, then the below sequence election requirement also is required. Additionally, if this group is elected, then the below specie election requirement also is required.

VI. Claims 23-30, drawn to methods of identifying compounds based on influencing the activity of a polypeptide via binding to said polypeptide; classified in Class 435, subclass 7.1. If this group is elected, then the below sequence election requirement also is required.

VII. Claims 31-33, drawn to methods of assaying compounds for the ability to reduce activity or level of a polypeptide via binding to a target coding sequence; classified in Class 435,

subclass 6. If this group is elected, then the below sequence election requirement also is required.

VIII. Claims 34, 47, 78, 84, 95, 102, and 107-110; drawn to compounds identified via coding sequence binding or gene product inhibition in activity or amount; classified in Class 514, subclasses 2 and 44. If this group is elected, then the below sequence election requirement also is required. Additionally, if this group is elected, then the below specie election requirement also is required.

IX. Claims 35-46, 68-77, 79-83, 85-94, and 96-101; drawn to methods of identifying compounds based on sensitized cell versus nonsensitized cell growth inhibition; classified in Class 435, subclass 6. If this group is elected, then the below sequence election requirement also is required. Additionally, if this group is elected, then the below specie election requirement also is required.

X. Claim 66, drawn to methods of identifying bacterial strains via probe binding; classified in Class 435, subclass 6. If this group is elected, then the below sequence election requirement also is required.

XI. Claims 67 and 103-105, drawn to methods of identifying a gene or pathway via inhibition of a gene or gene product; classified in Class 435, subclass 6. If this group is elected, then the below sequence election requirement also is required. Additionally, if this group is elected, then the below specie

election requirement also is required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of

this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

Additional specie election applicable only to Groups V, VIII, IX, and XI:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: inhibiting polypeptide gene product activity

Group V claims: 22 and 48

Group VIII claims: 47, 78, 84, 95, 102, and 107-109

Group IX claims: 35-44, 68-77, 79, 85-94, 96, 98, and 99

Group XI claims: 103-105

Specie B: reducing polypeptide gene product amount

Group V claims: 22, 48-51, and 54-65

Group VIII claims: 34, 47, 78, 84, 95, 102, and 107-109

Group IX claims: 35-46, 68-77, 79-83, 85-94, and 96-101

Group XI claims: 67 and 103-105

Specie C: inhibiting encoding nucleic acid activity

Group V claims: 22, 48-51, and 54-65

Group VIII claims: 34, 47, 78, 84, 95, 102, 108, and 110

Group IX claims: 35-46, 68-77, 79-83, 85-94, and 96-101

Group XI claims: 67 and 103-105

Specie D: reducing amount of encoding nucleic acid

Group V claims: 22 and 48

Group VIII claims: 47, 78, 84, 95, 102, 108, and 110

Group IX claims: 35-46, 68-77, 79-83, 85-94, 96, 98, and 99

Group XI claims: 103-105

The above species are distinct as they are directed to inhibition or influence at distinct steps in gene expression such as amount of encoding gene (Specie D), activity of gene, such as transcription (Specie C), amount of expressed polypeptide gene product (Specie B), and direct influence or inhibition of the polypeptide per se (Specie A). These each occur via different binding reactions and separately exert their influence on gene expression as a whole.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Group V claims 22 and 48; Group VIII claims 47, 78, 84, 95, and 102; Group IX claims: 35-44, 68-77, 79, 85-94, 96, 98, and 99; and Group XI claims 103-105 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R.

§ 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

The inventions of the above listed Restriction Groupings are distinct, each from the other because of the following reasons:

The inventions of Groups [I, IV, V(nucleic acid species), VII, VIII(nucleic acid species), IX(nucleic acid species), X, and XI(nucleic acid species)]; Groups [II, V(polypeptide species), VI, VIII(polypeptide species), IX(polypeptide species), and XI(polypeptide species)] ; and Groups [III, V(antibody polypeptide inhibitor species), VIII(antibody polypeptide inhibitor species), IX(antibody polypeptide inhibitor species), and XI(antibody polypeptide inhibitor species)] are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I etc. the critical feature is a nucleic acid; for Groups II etc. the critical feature is a polypeptide; and for Group III etc. the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups II etc. to be directed as to its synthesis by a nucleic acid of Groups I etc., however, the completely separate chemical types of the inventions

of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, nucleic acids, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I etc.); (II etc.); and (III etc.) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups IV, V(nucleic acid species), VII, VIII(nucleic acid species}, IX(nucleic acid species), X, and XI(nucleic acid species) are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups IV, V(nucleic acid species), VII,

VIII(nucleic acid species}, IX(nucleic acid species), X, and XI(nucleic acid species). These already document the distinct usages within the instant claims. One use is directed to polypeptide expression and the others to screening via nucleic acid binding or expression reactions.

The inventions of Group II and Groups V(polypeptide species), VI, VIII(polypeptide species), IX(polypeptide species), and XI(polypeptide species) are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group II can be used in the distinct processes of the inventions of Groups V(polypeptide species), VI, VIII(polypeptide species), IX(polypeptide species), and XI(polypeptide species) and in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing.

The inventions of Group III and Groups V(antibody polypeptide inhibitor species), VIII(antibody polypeptide inhibitor species), IX(antibody polypeptide inhibitor species), and XI(antibody polypeptide inhibitor species)] are related as product and distinct processes of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibodies of Group III can be used in the distinct processes of the inventions of Groups V(antibody polypeptide inhibitor species), VIII(antibody polypeptide inhibitor species), IX(antibody polypeptide inhibitor species), and XI(antibody polypeptide inhibitor species)] or, alternatively, in affinity purification or immunoassay processes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 25, 2001

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER